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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,787	02/22/2002	Robert A. Rabiner	20563/2052	1118
29934	7590	03/05/2004		
PALMER & DODGE, LLP RICHARD B. SMITH 111 HUNTINGTON AVENUE BOSTON, MA 02199			EXAMINER PANTUCK, BRADFORD C	
			ART UNIT 3731	PAPER NUMBER 8

DATE MAILED: 03/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/080,787

Applicant(s)

RABINER ET AL.

Examiner

Bradford C Pantuck

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 6 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/6-20-03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-21 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,692,139 to Stiles. Regarding Claims 1, 2, and 9-12 Stiles discloses a vascular introducer for insertion into a blood vessel. His introducer has an elongated shaft (1) and an anchoring mechanism (5). The anchoring mechanism (5) has a retracted position [see Fig. 1] and an extended position [see Fig. 3] in which the anchor is able to engage the inner surface of the artery [Column 3, lines 54-57]. Were anchoring mechanism inserted through a hole in the wall of a vessel just bigger than the diameter of elongated shaft (1), and the anchoring mechanism (5) put into an extended position, when the user pulls proximally (to retract the device), anchoring mechanism (5) will resist this movement, being lodged inside the vessel. Even though anchoring mechanism (5) is disclosed as intended for a different use by Stiles (of catching fragments of debris), it will serve as an anchor, and is able to be used as an anchor. Stiles' anchoring mechanism (5) is made out of rubber [Column 3, lines 38-39], and is capable of *securing the introducer*, as it is capable of becoming *lodged within a vessel or a hole in a vessel*.

Stiles also discloses an activation mechanism (2/3) that moves the anchoring mechanism (5) from the retracted position to the extended position. With reference to Figure 3, Stiles explains that to activate the anchoring mechanism (5) into a retracted position, the user should turn tube 3, which will rotate the anchoring mechanism (5), and in conjunction with the cooperating threads on the inside of the shaft (1), will cause the anchoring mechanism (5) to move distally, into the retracted position [Column 3, lines 30-39]. As explained in the preceding passage, the anchoring mechanism (5) is mounted on activating mechanism (3).

2. Regarding Claim 3, Stiles discloses a vascular introducer with an anchoring mechanism (5) that maintains contact between the vascular introducer and the blood vessel to prevent removal or detachment.
3. Regarding Claims 4 and 9, Stiles discloses a rotating mechanism that allows the vascular introducer to change direction within the blood vessel without being removed. By way of illustration, if one inserted the end of a pencil into a hole formed in a blood vessel, *one would be able to rotate it. There would be nothing preventing one from doing so.* The mechanism would merely be the end of the shaft (1), lubricated by the blood of the vessel. The absence of a protrusion, roughened section, or interfering component will allow the introducer (1) to be rotated.

Applicant does not claim any particular structure that does this, nor does he show in the pictures what such a mechanism should look like. Applicant discloses in the specification that the mechanism can be a ball-and-socket arrangement, a hinged arrangement, etc, but it is unclear how these mechanisms would function at the end of

the device. Regardless, Applicant has not set forth any of these specific mechanisms *within the claims*.

4. Regarding Claims 5-7, and 13-15, Stiles discloses an ultrasonic probe (6), shown clearly in Figure 3, inserted through the vascular introducer (1) into the blood vessel for ablation of debris inside the vessel [Column 2, lines 46-63]. The debris is an obstruction in the vessel [Column 2, lines 57-60] and is ablated by emitting ultrasonic energy [Column 1, lines 44-48].
5. Regarding Claims 8 and 16, the device is capable of being used once on a single patient and then discarded.
6. Regarding Claims 17-20, Stiles discloses a method of clearing debris from a blood vessel, including all of the mentioned steps. Stiles discloses placing the vascular introducer into the vascular access device, and ablating debris using the ultrasonic probe. The introducer need not be removed from the artery during ablation because a vacuum sucks the debris out through the tube (1) [Column2, lines 46-63].
7. Regarding Claim 21, Stiles discloses rotating the vascular introducer (1/3) within the vascular access device without removing the introducer 1/3) from the vascular access device. The introducer (1/3) is rotated relative to component (9) at its proximal end [Column 4, lines 37-41].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S.

Patent No. 6,494,893 to Dubrul et al. in view of U.S. Patent No. 5,971,983 to Lesh.

Dubrul discloses a vascular introducer (20) with an anchoring mechanism (72) into a vascular access device. The vascular introducer is hollow to accommodate various needles and other surgical devices [Column 8 line 53 – Column 9 line 10]. Dubrul discloses engaging an anchoring mechanism (72) [Column 7, lines 36-45; Column 8, lines 1-13] to the inner surface of the vascular access device at a puncture site [Column 9, lines 8-14; see Fig. 17]. Such an anchoring system would be atraumatic.

Regarding Applicant's definition of the term "vascular access device," the specification defines this term very broadly. On page 11, lines 14 and 15, Applicant explains, "Vascular access device as used herein refers generally to any graft, fistula, vessel, access port or *other device providing access to a vascular system of a patient*" [emphasis added by Examiner]. Examiner interprets the scope as being any device or vessel in the body or outside of the body that connects to the vasculature of the patient. Therefore, since Dubrul's device is intended to be anchored through the skin and flesh of a patient (particularly in such places as the chest of the patient), his device is intended for attachment to such vessels as the chest cavity, the abdominal cavity, and the urethra [Column 1, lines 50-52]. Dubrul does not disclose inserting an ultrasonic probe through his trocar.

However, Lesh discloses a trocar and anchoring assembly and teaches inserting an ultrasonic probe through his assembly and into a vascular access device (such as the heart or other body organs). He does so in order to ablate debris [Column 9, lines 55-61]. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use an ultrasonic probe in conjunction with a trocar (vascular introducer) in order to ablate tissue, as taught by Lesh.

9. Claims 17-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,707,359 to Bufalini in view of U.S. Patent No. 5,971,983 to Lesh. Regarding Claims 17, 20, 25, and 31, Bufalini discloses a vascular introducer (32) with an anchoring mechanism (36) into a vascular access device (56). The vascular introducer is hollow to accommodate the removal of various internal organs therethrough [Column 1, lines 25-36]. Bufalini illustrates engaging an anchoring mechanism (36) to the inner surface of the vascular access device at a puncture site in Figure 8. Such an anchoring system would be atraumatic. Bufalini does not disclose inserting an ultrasonic probe through his trocar.

However, Lesh discloses a trocar and anchoring assembly and teaches inserting an ultrasonic probe [Column 15, lines 20-60] through his assembly and into a vascular access device (such as the heart or other body organs). He does so in order to ablate debris [Column 9, lines 55-61]. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use an ultrasonic probe in conjunction with the trocar of Bufalini (vascular introducer) in order to ablate tissue, as taught by Lesh.

10. Regarding Claim 18, the vascular access device is a vessel (the abdominal cavity) [Column 1, lines 34-37; Column 4, lines 19-25].
11. Regarding Claims 19 and 27, the debris is a lesion, which is a diseased portion of a tissue that can often cause blockages [Column 4, lines 52-58].
12. Regarding Claims 21 and 26, Lesh discloses a stylet (5) ablation wire similar to Applicant's component (30) that extends through the lumen of his device and out the distal end [Column 15, lines 36-40]. Lesh teaches that the user should "sweep" the ablation element "like a compass" [Column 15, lines 56-60] in order to ablate various parts of the tissue.
13. Regarding Claims 22 and 28, the anchor will maintain contact with the abdominal wall, as the specimens are extracted through the vascular introducer (32) because of the force. Figure 8 shows the anchor (36) in contact with the wall, and the anchor is too big to fit through the hole in the vascular access device (56).
14. Regarding Claims 23, 24, 29, and 30 the anchor is retractable and extendable when activation mechanism (50) moves, as shown in the progression from Fig. 7 to Fig. 8.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 6,530,923 B1 to Dubrol

Publication No. US 2002/0007130 A1 to Burbank et al.

U.S. Patent No. 5,443,456 to Alliger et al.

U.S. Patent No. 5,971,960 to Flom et al.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Response to Arguments

16. Applicant's arguments filed February 12, 2004, with respect to the rejection under Stiles, have been fully considered but they are not persuasive. Stiles discloses all of the structure claimed by the applicant. Applicant does not positively recite an ultrasonic probe, but only states that the device is capable of having one inserted therethrough. Stiles' device is capable of being used at the puncture site, and would be atraumatic because of anchor (5). The term "vascular access device," as defined in the specification is quite broad.

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17. Applicant's arguments, see page 13 lines 1-14, filed February 12, 2004, with respect to the rejection under Cragg have been fully considered and are persuasive. The rejection of claims 1-4, 8-12, and 16 under Cragg has been withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BCP
BCP
March 2, 2004


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SUPERVISORY PATENT EXAMINER
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